Brian M. English
Matthew P. O'Malley
TOMPKINS, MCGUIRE,
WACHENFELD & BARRY, LLP
Four Gateway Center
100 Mulberry Street, Suite 5
Newark, N.J. 07102-4056
Tel. (973) 623-7491
Fax (973) 623-7481
benglish@tompkinsmcguire.com

Attorneys for Plaintiffs sanofi-aventis Deutschland GmbH, Aventis Pharma S.A., Abbott GmbH & Co. KG, Abbott Laboratories and Abbott Laboratories Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SANOFI-AVENTIS DEUTSCHLAND GMBH, AVENTIS PHARMA S.A., ABBOTT GMBH & CO. KG, ABBOTT LABORATORIES and ABBOTT LABORATORIES INC., Plaintiffs, v. GLENMARK PHARMACEUTICALS INC., USA, and GLENMARK PHARMACEUTICALS LTD. Defendants.	Civil Action No. 07-CV-05855 (DMC-JAD)

PLAINTIFFS' MOTION FOR JUDGMENT AS A MATTER OF LAW FOR OBVIOUSNESS-TYPE-DOUBLE PATENTING

INTRODUCTION

Glenmark cannot prove its defense of obviousness-type double patenting. As a matter of law, Glenmark's obviousness-type double patenting fails because the patent-in-suit falls squarely within the safe-harbor provision of 35 U.S.C. § 121. No reasonable jury could find otherwise.

"When the PTO requires an applicant to withdraw claims to a patentably distinct invention (a restriction requirement), § 121 shields those withdrawn claims in a later divisional application against rejection over a patent that issues from the original application." *Boehringer Ingelheim Int'l GmbH v. Barr Labs., Inc.*, 592 F.3d 1340, 1350 (Fed. Cir. 2010). Here, the U.S. Patent and Trademark Office ("PTO") issued a restriction requirement dividing the claims of the original patent application because they were "independent and distinct" inventions. Dr. Becker complied with this PTO directive. Accordingly, he pursued his claims to the combination of ramipril and a calcium antagonist in the application that became U.S. Patent No. 5,098,910 ("the '910 patent"). He withdrew his claims to combinations with trandolapril and quinapril and pursued what became claim 3 in a separate application. Claim 3, pursued in that separate application in compliance with the PTO's directive, issued as U.S. Patent No. 5,721, 244 ("the '244 patent).

Accordingly, the § 121 safe harbor applies and the claims of the '910 patent cannot be used against the '244 patent's claim 3. Therefore, as a matter of law, obviousness-type double patenting cannot apply and judgment as a matter of law regarding obviousness-type double patenting is appropriate.

ARGUMENT

I. STANDARD FOR GRANTING JUDGMENT AS A MATTER OF LAW

"Rule 50(a) provides that a court may grant judgment as a matter of law in a jury trial at the close of the evidence if it determines that there is no legally sufficient evidentiary basis for a reasonable jury to find for a party on an issue." *Rego v. ARC Water Treatment Co. of Pennsylvania*, 181 F.3d 396, 400 (3rd Cir. 1999)*; see also Pannu v. Iolab Corp.*, 155 F.3d 1344, 1348 (Fed. Cir. 1998) (discussing standard for renewed motion for judgment as a matter of law following a jury's verdict).

II. THE § 121 SAFE HARBOR APPLIES

Judgment as a matter of law is appropriate because 35 U.S.C. § 121 provides a safe-harbor from a finding of obviousness-type double patenting in the very situation presented here. "When the PTO requires an applicant to withdraw claims to a patentably distinct invention (a restriction requirement), § 121 shields those withdrawn claims in a later divisional application against rejection over a patent that issues from the original application." *Boehringer Ingelheim Int'l GmbH v. Barr Labs., Inc.*, 592 F.3d 1340, 1350 (Fed. Cir. 2010). "[A] patent need not have issued directly from a divisional application to receive § 121 protection. In other words, intervening continuation applications do not render a patent ineligible for § 121 protection so long as they descended from a divisional application filed as a result of a restriction requirement." *Amgen Inc. v. F. Hoffman-LA Roche Ltd*, 580 F.3d 1340, 1354 (Fed. Cir. 2009). The PTO required Dr. Becker to withdraw claims to a patentably distinct invention. His claim 3 at issue was filed as a result of a restriction requirement. As a result, *Boehringer Ingelheim* applies and claim 3 and obviousness-type double patenting cannot be found.

1. The PTO Directed Dr. Becker to Separate the '910 and '244 Claims and to File a Divisional Application

On September 30, 1987, Dr. Becker along with his four inventor colleagues at Hoechst A.G. submitted their original U.S. patent application claiming combinations of double-ring and triple-ring ACE inhibitors with calcium antagonists to the PTO. (PTX 6 at SA0000183-221.) The original application included claims for the double-ring ACE inhibitors, including claim 5 for ramipril and a calcium antagonist, claim 6 for trandolapril and a calcium antagonist, and claim 7 for quinapril and a calcium antagonist. (*Id.* at SA0000213)

During the prosecution of the application, the PTO required that Dr. Becker divide up the inventions into separate patents – a common procedure at the PTO called a "restriction requirement." (Trial Tr. Vol. 3 at 51:20 – 52:16; PTX 5 at SA 0000540-541.) In an Office Action dated January 5, 1990, the PTO issued a restriction requirement, noting this action by checking the box on the first page of the Office Action: "Claims 1-32 are subject to restriction or election requirement." (*Id.* at SA 0000540.) The PTO Examiner specifically noted: "[t]his application contains claims to more than one synergistic combination of the generic invention." (*Id.* at SA 0000541.)[1] The PTO Examiner required the inventors to choose one invention to pursue in the first patent application, or as the examiner stated, "the response to this requirement to be complete must include an election of the invention to [be] examined." (*Id.*)

In response to the PTO's restriction requirement, in a paper dated April 17, 1990, Dr. Becker elected to pursue a combination with the ACE inhibitor ramipril. (*Id.* at SA 0000543.) Claims to other combinations, such as the trandolapril and quinapril combinations

[1] The examiner stated that "[t]he inventions above are independent and distinct and one does not require the other for ultimate use. They have different fields of search which are not coextensive. It is also noted that one specific synergistic combination of two compounds is known to be chemically distinct from another specific synergistic combination of two compounds, and a reference to one combination would not necessarily be a reference against another combination under 35 USC 103." (*Id.*)

claimed in claims 6 and 7 of the original application, were withdrawn from consideration. (*Id.*) The examiner formally acknowledged Dr. Becker's withdrawal of claims 6 and 7. (Office Action dated June 22, 1990 (*Id.* at SA 0000548).) The elected ramipril-calcium antagonist combination claims issued as U.S. Patent No. 5,098,910 ("the '910 patent"). (DTX 3.) Claim 4 of the '910 patent, on which Glenmark relies, recites a combination of ramipril and a calcium antagonist. (*Id.* at col. 17-18.)

At the time of the restriction requirement, what is now issued claim 3 of the '244 patent claiming trandolapril or quinapril was separately claimed in the pending application by claim 6 (for trandolapril and a calcium antagonist) and claim 7 (for quinapril and a calcium antagonist). (PTX 5 at SA 0000472.) On December 20, 1990, Dr. Becker filed U.S. Patent Application No. 07/811,149 as a divisional application of the '910 patent. (PTX 4.) The divisional application pursued ACE inhibitor-calcium-antagonist-combination claims for trandolapril, quinapril and related structures. (*Id.* at SA 0000344.) Claims 6 and 7 from the original 1987 patent application, covering combinations with trandolapril and quinapril, respectively, were combined into a single claim. (SA 0000381.)

After several Office Actions, Dr. Becker filed a continuation application on April 11, 1994. (PTX 3.) Continuation applications allow an inventor to continue the negotiations with the PTO to obtain issuance of the patent claims by paying an additional fee to obtain further examination of the application. (*Id.* at SA 0000655.) Dr. Becker filed a subsequent continuation application on June 7, 1995. (PTX 2.) On February 24, 1998, the PTO issued the '244 patent containing claim 3 covering combinations of trandolapril and quinapril with a calcium antagonist. (PTX 1.)

2. The PTO Issued a Double Patenting Rejection, and Withdraws It

The virtually-identical obviousness-type-double-patenting issue was already considered by the PTO, and the PTO found that the safe harbor applies. On July 13, 1994, the PTO rejected the pending claims for trandolapril and the calcium antagonist felodipine on grounds of double patenting over the '910 patent's claims. (PTX 3, SA 0000672).

In response, Dr. Becker's attorney reminded the PTO that it had ordered division of the claims in a restriction requirement. (Response dated Oct 13, 1994 (*Id.* at SA 0000702).) In response to this reminder, the PTO withdrew its obviousness-type double patenting. (Office Action dated Jan. 3, 1995 (SA 0000707-710).)

3. As A Matter Of Law Obviousness-Type Double Patenting Does Not Apply to Claim 3 of the '244 Patent.

"The safe harbor is provided to protect an applicant from being penalized for dividing an application." *Boehringer Ingelheim*, 592 F.3d at 1354. Yet, this is what Glenmark's defense seeks to accomplish – to penalize Dr. Becker and his colleagues for following the directive of the PTO to divide the original application into separate patents.

The situation here falls squarely within the safe harbor of § 121. "When the PTO requires an applicant to withdraw claims to a patentably distinct invention (a restriction requirement), § 121 shields those withdrawn claims in a later divisional application against rejection over a patent that issues from the original application." *Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1378 (Fed. Cir. 2003). The PTO made just such a restriction requirement in the ’910 patent application. As a result, the claims to the trandolapril and quinapril combinations were withdrawn and the inventors refiled them in a divisional application, as requested by the examiner. These claims to the trandolapril and quinapril combinations ultimately issued as claim 3 in the ’244 patent.

Section 121 protections depend on three factors, all of which are met here. First, the division of the claims into separate patents must have been the result of a restriction requirement. *Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1378 (Fed. Cir. 2003). Although Glenmark disputes this element, the file history is in evidence and includes an explicit restriction requirement, with a "restriction requirement" box checked by the examiner. (PTX5 at SA 0000540.) Moreover, the PTO conceded that it issued a restriction requirement when it withdrew its own obviousness-type double patenting rejection. (PTX3 at SA 0000707-710.)

Second, the PTO never withdrew the restriction requirement. Once the restriction requirement issued, the PTO instructed the Applicants to withdraw the claims pertaining to trandolapril and quinapril combinations. (PTX5 at SA 0000548.) The restriction requirement remained in effect throughout the prosecution of the '910 patent.

The third requirement is called "consonance," and is the principal requirement disputed by Glenmark. "Consonance requires that the line of demarcation between the 'independent and distinct inventions' that prompted the restriction requirement be maintained. Though the claims may be amended, they must not be so amended as to bring them back over the line imposed in the restriction requirement." *Symbol Technologies, Inc. v. Opticon, Inc.*, 935 F.2d 1569, 1579 (Fed. Cir. 1991).

The consonance analysis here is trivial. The claims ordered to be removed by the examiner recite trandolapril with a calcium antagonist, and quinapril with a calcium antagonist. The '244 patent's claim 3 combines both claims into one, but otherwise provides the same coverage. By contrast, the '910 patent claims concerns only ramipril and its combination with a calcium antagonist. Thus, the line of demarcation is necessarily maintained between the '910 patent and the '244 patent.

In sum, the evidence of record shows that the '244 patent meets the requirements for the Section 121 "safe harbor." Moreover, the record further shows that the PTO considered the issue of obviousness-type double patenting and concluded that the Section 121 Protection applies. Accordingly, the claims of the '910 patent cannot be asserted against the '244 patent and obviousness-type double patenting is inapplicable. Therefore, in view of the facts presented and the controlling law, no reasonable jury could find that claim 3 is invalid under the doctrine of obviousness-type double patenting and judgment as a matter of law is required.

B. Claim 3 of the '244 Patent is Not an Obvious Variant of Claim 4 of the '910 patent.

Aside from the Section 121 "safe harbor" protection, the evidence further shows that no reasonable jury could find claim 3 to be an obvious variation under the double-patenting standard. "The primary inquiry in double patenting cases is therefore whether the claims in the latter patent are more than a 'slight variant' from the claims in the earlier patent." *Eli Lilly and Co. v. Teva Pharmaceuticals USA, Inc.*, 619 F.3d 1329, 1341 (Fed. Cir. 2010). Here, the undisputed facts show that the claim 3 of the '244 patent is not an obvious variant of claim 4 of the '910 patent.

Claim 4 of the '910 patent claims a combination of ramipril and a calcium antagonist. (DTX3 at col. 17.) It does not claim a pharmaceutical composition comprising quinapril or trandolapril. The '244 patent's claim 3 differs from the '910 patent's claim 4. Claim 3 covers only combinations containing trandolapril or quinapril with a calcium antagonist. It does not claim a combination containing ramipril as set out in claim 4 of the '910 patent.

Claim 4 of the '910 patent does not teach or suggest to one of ordinary skill in the art to select either trandolapril or quinapril in a combination with a calcium antagonist. Trandolapril and quinapril are not mentioned in claim 4. As acknowledged by the PTO, the combinations of

ramipril and a calcium antagonist in the '910 patent and the combinations of trandolapril or quinapril with a calcium antagonist "are independent and distinct," and "a reference to one combination would not necessarily be a reference against another combination under 35 USC 103" for obviousness. Therefore, no reasonable jury could find that claim 3 is an obvious variant of claim 4 of the '910 patent

CONCLUSION

The PTO required Dr. Becker to divide his inventions into two separate patents. Accordingly, Section 121 shields the resulting '244 patent from obvious-type double patenting. As the PTO determined, the claims of the '910 and '244 patents are "independent and distinct" inventions. Accordingly, Plaintiffs request that the Court enter judgment as a matter of law on Glenmark's defense of obviousness-type double patenting.

January 12, 2011

Respectfully submitted:

By: /s/ Brian M. English

Brian M. English
Matthew P. O'Malley
TOMPKINS, MCGUIRE,
WACHENFELD & BARRY, LLP
Four Gateway Center
100 Mulberry Street, Suite 5
Newark, N.J. 07102-4056
Tel. (973) 623-7491
Fax (973) 623-7481
benglish@tompkinsmcguire.com

Attorneys for Plaintiffs sanofi-aventis Deutschland GmbH, Aventis Pharma S.A., Abbott GmbH & Co. KG, Abbott Laboratories and Abbott Laboratories Inc.

OF COUNSEL:

Benjamin C. Hsing

John Allcock

Sapna W. Palla
KAYE SCHOLER LLP
425 Park Avenue
New York, New York 10022
Tel. (212) 836-8000
Fax. (212) 836-8689

Attorneys for Plaintiffs
sanofi-aventis Pharma Deutschland GmbH and Aventis Pharma S.A.

Erica Pascal
DLA Piper LLP (US)
401 B Street, Suite 1700
San Diego, California 92101
Tel. (619) 699.2639 T
Fax (619) 699.2701 F

Stuart E. Pollack
DLA Piper LLP (US)
1251 Avenue of the Americas
New York, New York 10020-1104
Tel. (212) 335 4964
Fax (212)884 8464

Attorneys for Plaintiffs
Abbott GmbH & Co. KG, Abbott Laboratories and Abbott Laboratories Inc.